

## REMARKS

### I. Status of the Claims

Claims 1-25 are pending in the application, are under examination and stand rejected under 35 U.S.C. §102 and §103. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

### II. Objections

Claims 4 and 15 are objected to as not limiting the claims from which they depend. The claims have been canceled, rendering the objection moot.

### III. Rejections Under 35 U.S.C. §102

#### A. *Shinal et al.*

Claims 1, 3, 4, 7-10, 12-17, 24 and 25 are rejected as anticipated by *Shinal et al.* Applicants traverse, but in the interest of advancing the prosecution, claims 1 and 13 have been amended to recite the elements of claim 11, which was not previously rejected. Similarly, claim 24 has been amended to include a pudding and a mold. As such, applicants believe that the examiner would agree that all of the remaining claims are novel over *Shinal et al.* Reconsideration and withdrawal of the rejection is therefore requested.

#### B. *Sherratt et al.*

Claims 1, 2, 5 and 6 are rejected as anticipated by *Sherratt et al.* Applicants traverse, but in the interest of advancing the prosecution, claims 1 and 13 have been amended to recite the elements of claim 11, which was not previously rejected. As such, applicants believe that the

examiner would agree that all of the remaining claims are novel over Shinal *et al.* Reconsideration and withdrawal of the rejection is therefore requested.

#### **IV. Rejection Under 35 U.S.C. §103**

Claims 11, 18 and 23 are rejected as obvious over Shinal in view of Sherratt. The references are essentially cited as above. Though Shinal teaches glutamine in popsicles, and Sherratt mentions glutamine and puddings, applicants nonetheless traverse the rejections for the following reasons.

The present invention, as now claimed, combines several features that lead to improved results in the delivery of L-glutamine to patients. First, it should be pointed out that while Shinal teaches delivery of L-glutamine in popsicles, it does not teach puddings. The question then would be whether one of skill in the art would turn to Sherratt for puddings. Applicants submit that one would *not* turn to Sherratt for the simple reason that Sherratt deals with formulations to *increase* the uptake of glutamine, and hence *decrease* the amount of glutamine to be delivered to a subject. Thus, the examiner's assumption that the skilled artisan, understanding that the point of Shinal is to increase a patient's intake of L-glutamine through more desirable delivery vehicles, would turn to Sherratt, whose point was to *decrease* the delivery of L-glutamine by increasing uptake, is incorrect.

Even if one were to combine the two references, applicants submit that a *prima facie* case would be effectively rebutted by surprising and unexpected benefits of the claimed frozen pudding compositions. In the development of the present invention, the inventors first combined only L-glutamine with frozen water in a popsicle mold. This resulting in precipitation (or clumping) of L-glutamine in the bottom of each popsicle. When the popsicles were removed from the mold, this precipitation was visually obvious as a white clump at the uppermost tip of


the popsicle (*i.e.*, representing the bottom of the popsicle when inverted in the mold), which caused the popsicle to be unpalatable. As a result, a number of different mediums were tested in an attempt to “suspend” the L-glutamine and prevent precipitation. The inventors finally found that pudding would provide the necessary medium to suspend the L-glutamine and provide a uniform dispersion throughout. The attached declaration from the inventor provides the details experimental details.

In sum, applicants submit that due to the difficulties associated with preparing a palatable formulation of L-glutamine, and the unpredictable benefit associated with the use of pudding as a medium, obviousness is not found here. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

**V. Conclusion**

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



Steven L. Highlander  
Reg. No. 37,642  
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
(512) 474-5201

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